

EXHIBIT K

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION**

**Master File No. 2:12-MD-2327
MDL No. 2327**

THIS DOCUMENT RELATES TO:

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

Nancy Hooper, et al. v. Ethicon, Inc., et al.
Case No. 2:12-cv-00493

EXPERT REPORT OF DR. VLADIMIR IAKOVLEV

My general opinions on the Gynemesh mesh product can be found in my general Rule 26 report for all Ethicon products in this MDL, and is incorporated by reference herein.

**CLINICO-PATHOLOGICAL CORRELATION OF COMPLICATIONS
EXPERIENCED BY MRS. NANCY HOOPER**

This section of the report provides a case-specific assessment. The complete report includes a separately provided general part and the provided herein case-specific section. My opinions are based on both, the case specific assessment and the knowledge and experience I gained through the assessment of other implantable transvaginal devices, including those manufactured by Ethicon.

Summary of clinical records

I reviewed clinical records of Mrs. Nancy Hooper. The records were screened focusing on:

- Events and symptoms with temporal relationship to mesh placement, alteration, or excision
- Symptoms, procedures and results of investigations that potentially could be Anatomically and pathophysiologically related to the urogenital area and the mesh
- Alternative medical conditions, procedures and results of investigations that potentially could cause or explain symptoms and complications attributed to the mesh and related procedures in error.

Diagnosis:

A. Right tube/ovary:

Atrophic-appearing ovary with several small benign surface inclusion cysts.

Fallopian tube with small benign paratubal cysts.

Tubo-ovarian adhesions.

B. Left fallopian tube:

Fallopian tube with small benign paratubal cysts.

C. Sacrocolpopexy mesh:

Surgical mesh with adherent reactive fibrous tissue showing mild chronic inflammation and foreign body reaction.

Gross:

A. Received is a container labeled Nancy Hooper, right ovary/tube. A portion of rubbery tan-pink and pink-white tissue 3.4 x 2.8 x 1.3 cm, is focally roughened and mottled red-brown over the surface. The specimen is serially sectioned and submitted as blocks 1-3. (7b/3c)

B. Received is a container labeled Nancy Hooper, left fallopian tube. A fimbriated portion of fallopian tube, 3.6 cm in length averages 0.7 cm in diameter, is focally roughened over the external surface. Sectioned surfaces are grossly not unusual and representative sections are submitted as block 1. (3b/1 c)

C. Received is a container labeled Nancy Hooper, sacrocolpopexy mesh. A Y-shaped portion of sacrocolpopexy mesh is overall 4.9 x 4.7 x 0.3 cm and is partially encapsulated by strands of rubbery tan-pink and red-brown tissue. A representative section of soft tissue is submitted as block 1 and the specimen is returned to risk management to be returned to the "attorney's office".

Microscopic description:

1. Sections of the original slides prepared at the Parkridge Hospital showed a portion of excised mesh within maturing granulation tissue (loose inflamed scar tissue) (Figure NH1). The tissue had moderately dense chronic non-specific inflammation. There were also fragments of tissue from the peritoneal (abdominal) cavity, reactive serosal surface and/or parts of the fallopian tube (Figures NH2&3). These fragments were in keeping

with the intraoperative description of mesh exposure through peritoneum and involvement of the right fallopian tube.

2. The material received in the container consisted of mesh and incorporating it dried tissue (Figure NH4). The material was divided in half, $\frac{1}{2}$ was retained by the defense expert and the other $\frac{1}{2}$ was processed as a routine consultation case of St. Michael's hospital. Sections of the specimen portion processed at St. Michael's hospital showed tissue affected by drying. There was monofilament mesh embedded in scar tissue (Figure NH5). Some parts of the mesh were incorporated by the tissue in folded configuration. There was a cellular zone around the mesh fibers consistent with foreign body type inflammatory reaction (Figure NH6). One part of the mesh had density of inflammation similar to the fragment seen in the earlier processed part of the specimen (Figure NH7).

Polypropylene degradation:

At high magnification the mesh fibers in both, slides prepared at the Parkridge and St. Michael's hospitals showed an outer layer of degraded polypropylene (Figures NH8-10). The degraded material absorbed histological dyes and stained purple in H&E stained sections while the non-degraded core remained clear. Although altered, the degraded material retained birefringence (brightness in polarized light) of polypropylene. The layer of degraded polypropylene showed cracking and peeling indicating its brittleness.

There were no pathological findings of natural, non-mesh related diseases or another foreign body in either part of the specimen (slides prepared at the Parkridge and St. Michael's hospitals)

Clinico-pathological correlation

Mrs. Hooper had sacral colpopexy with Gynecare Gynemesh in December 2010. Six weeks later she presented with bowel obstruction and was taken to OR. The small bowel was found to be affected by adhesions in the pelvis, at the area described as "suture" at the time. Later in 2011 Ms. Hooper continued to have persistent abdominopelvic pain and painful bowel

I reserve the right to supplement this report if new information becomes available. My billing rate is \$475 per hour.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Vladimir Iakovlev', with a stylized flourish at the end.

Vladimir Iakovlev, MD, FRCPC, FCAP

DATE: January 26, 2016